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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/069,681	12/02/2002	Nathalie Claude Marianne Barges	P32396	3820
20462	7590	12/16/2004	EXAMINER	
SMITHKLINE BEECHAM CORPORATION CORPORATE INTELLECTUAL PROPERTY-US, UW2220 P. O. BOX 1539 KING OF PRUSSIA, PA 19406-0939			GEORGE, KONATA M	
		ART UNIT	PAPER NUMBER	
		1616		

DATE MAILED: 12/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/069,681	BARGES ET AL.
	Examiner Konata M. George	Art Unit 1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_ is/are allowed.
- 6) Claim(s) 1,2,4 and 7-13 is/are rejected.
- 7) Claim(s) 3,5,6 and 14-18 is/are objected to.
- 8) Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 19 February 2002 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |                                                                                                                                    |                                                                             |
|------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                               | Paper No(s)/Mail Date. ____ .                                               |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____ . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|                                                                                                                                    | 6) <input type="checkbox"/> Other: ____ .                                   |

**DETAILED ACTION**

Claims 1-18 are pending in this application.

***Information Disclosure Statement***

1. The information disclosure statement (IDS) submitted on February 19, 2002 was noted and the submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner has considered the information disclosure statement.

***Drawings***

2. The drawing(s) filed February 19, 2002 under 37 CFR 1.184 or 1.152 are accepted by the examiner.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 4 and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 4 is unclear to the examiner, if there is a difference between natural flavoring substances and Nature-identical flavoring substances. Please explain the differences. Claim 7 is unclear to the examiner with respect to the base as claimed by applicant. The specification does not reasonably define what the base is.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 2 and 8-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Martin et al. (5,851,550).

Martin et al. describes in Example 9, column 8, lines 40-67, a granulate composition comprising amoxycillin trihydrate and potassium clavulanate in a weight ratio of about 4:1. The composition also contains a pharmaceutically excipient polyplasdone XL (CLPVP) and dried flavoring agents (i.e. strawberry). It is also taught that the composition can also contain additional flavoring agents (i.e. peach). Column 5, lines 1-3 teach that the granulate composition forms a loose compact which in turn allows for rapid dispersion in contact with water for oral administration. Although there are no examples of the amoxycillin:clavulanate having a ratio of 2:1, it is taught in column 1, lines 55-56 that it may be formulated having that ratio. Column 3, line 66 teaches a granulate formulation that contains silica gel in a concentration of 0-30 weight %. Furthermore, although, example 9, column 8 teaches a granulate composition comprising 16.8% of the silica gel which is outside of the claimed range, it is the position of the examiner that when the flavor agents are added to the composition then the concentration will drop and fall within the claimed range. The same rational is used with

respect to the concentration of the silica gel. Example 8, column 8, lines 5-19 teach a composition comprising amoxycillin trihydrate and potassium clavulanate together with a flavor agent and a sweetening agent (i.e. aspartame).

#### ***Allowable Subject Matter***

5. Claims 3, 5, 6 and 14-18 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The cited prior art does not disclose the formulation comprising a creamy note comprising a blend of vanillin, maltol (ethyl maltol), δ-dodecalactone, furonol and diacetyl as claimed in claim 3. It is also not taught that the major components of the flavors are furonol, maltol, ethyl vanillin, etc. as claimed in claim 5. It is not taught by the prior art that formulation has a matching flavor. It is not taught by the prior art that formulation comprises extra-granule excipients comprising silica gel, carboxymethylcellulose sodium salt, xanthan gum, sodium benzoate, colloidal silica magnesium stearate and a sweetener as claimed in claim 14. It is not taught by the prior art the specific formulations as claimed in claims 15 and 16. Finally, it is not taught that the silica gel of claim 14 is in a concentration of from 8 to 12% and that the composition contains as a sweetening agent, aspartame as claimed in claims 17 and 18.

#### ***Conclusion***

6. Claims 1, 2, 4 and 7-13 are rejected.

***Telephone Inquiries***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konata M. George, whose telephone number is (571) 272-0613. The examiner can normally be reached from 8AM to 6:30PM Monday to Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached at (571) 272-0887. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Konata M. George

*Gary D. Kunz*  
GARY KUNZ  
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